DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claim 51 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim improperly recites human tissue as part of the claimed invention. It is suggested that the Applicant amend the claim to include the phrase "configured to be positioned" or "adapted to be positioned" in order to remove human tissue from the claimed invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2, 31, 32, 38, 39, 43, 45, 47, 65 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by McClelland et al.'215 (cited by Applicant).

McClelland et al.'215 discloses an apparatus for infrared spectroscopy that includes a spectrometer/detector 18, an infrared transmissive window 14/14', and a heating/cooling element 16/16' (see descriptions of Figures 1 and 3 in cols. 5-7). Although McClelland et al.'215 does not disclose performing measurements on tissue samples, the device disclosed above is structurally

indistinguishable from a spectroscopic analyzer for performing measurements on a tissue sample (flowing blood). Therefore, the reference is considered to meet the claimed limitations. Regarding claim 72, it is noted that in disclosing a device such as the one described above, McClelland et al.'215 inherently discloses a method of making a device wherein each of the discussed elements is provided.

5. Claims 1, 2 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Block'953 (cited by Applicant).

Figure 2 of Block'953 discloses an apparatus that includes an infrared detector 24, an infrared filter 26 (considered to be an infrared transmissive window), a cooling unit 28 and a temperature controller 30, wherein the temperature controller is a means for inducing a temperature gradient in a subject (col. 8, line 37 – col. 9, line 15).

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claim 101 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 9 of prior U.S. Patent No. 6,633,771. This is a double patenting rejection.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 2, 31, 32, 38 and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 6,072,180. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the current application are broader in scope than the claim of the US Patent. Therefore, any device meeting the limitations set forth in the claim of the patent would also meet the limitations set forth in the claims of the current application.

10. Claims 1, 2, 11, 31, 32, 38, 39, 45, 47, 51 and 102-107 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 28, 29, 41, 58 and 59 of U.S. Patent No. 6,633,771. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the current application are broader in scope than the claims of the US Patent. Therefore, any device meeting the limitations set forth in the claims of the patent would also meet the limitations set forth in the claims of the current application.

Allowable Subject Matter

11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teaches or suggests, either alone or in combination, a device comprising an infrared transmissive thermal insulating material, in combination with the other claimed elements.

12. Claims 82-100 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB